

ISO 19609-1:2021 (E)

Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 1: General requirements

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Overview of herbal medicinal products
4.1	Raw materials
4.2	Products of raw materials
4.2.1	General
4.2.2	Decoction pieces, medicinal decoctions prepared from decoction pieces and wine preparations or powders
4.2.3	Finished products for modernized traditional therapy
4.2.4	Non-traditionally produced finished products for phytotherapy
5	Quality testing
5.1	General
5.2	Testing procedure
6	Testing of physical parameters
6.1	General
6.2	Sampling
6.2.1	General
6.2.2	Bulk sampling method
6.2.3	Test sampling method
6.2.3.1	General
6.2.3.2	Apparatus
6.2.3.3	Procedure for producing specific test samples
6.2.3.3.1	Quartering
6.2.3.3.2	Test for foreign matter
6.2.3.3.3	Preparing test samples for chemical and chromatographic analysis
6.2.3.3.4	Preparing test samples for determination of microscopic characters
6.3	Estimation of the water content of herbals and resulting products
6.3.1	General
6.3.2	Testing methods
6.3.2.1	General
6.3.2.2	Loss on drying
6.3.2.2.1	General
6.3.2.2.2	Sample preparation
6.3.2.2.3	Reagents
6.3.2.2.4	Apparatus
6.3.2.2.5	Method for raw materials and products with no or low content of essential oils
6.3.2.2.6	Method for raw materials and products with higher content of essential oils
6.3.2.2.7	Method for raw materials and products with unstable constituents
6.3.2.3	Quantitative analysis of water content
6.3.2.3.1	General
6.3.2.3.2	Determination of water with gas chromatography with thermal conductivity detector (TCD)
6.3.2.3.2.1	Sample preparation

6.3.2.3.2.2	Reagents
6.3.2.3.2.3	Apparatus
6.3.2.3.2.4	Procedure and analytical conditions
6.4	Requirements and testing methods for finished products for modernized traditional therapy and non-traditionally produced finished products for phytotherapy
6.4.1	General
6.4.2	Estimation of the uniformity of dosage units
6.4.2.1	Estimation of the uniformity of mass
6.4.2.1.1	Apparatus
6.4.2.1.2	Procedure
6.4.2.1.3	Calculation
6.4.2.2	Estimation of the uniformity of mass of delivered doses from multidose containers
6.4.2.2.1	General
6.4.2.2.2	Apparatus
6.4.2.2.3	Procedure
6.4.2.2.4	Calculation
6.4.3	Disintegration test for solid dosage forms like tablets and capsules
6.4.3.1	General
6.4.3.2	Apparatus
6.4.3.2.1	Disintegration apparatus
6.4.3.2.2	Basket-rack assembly A for tablets and capsules of normal size not greater than 18 mm
6.4.3.2.3	Basket-rack assembly B for tablets and capsules greater than 18 mm
6.4.3.2.4	Discs for basket-rack assembly A for tablets and capsules of normal size not greater than 18 mm
6.4.3.2.5	Discs for basket-rack assembly B for tablets and capsules greater than 18 mm
6.4.3.3	Procedure
6.4.3.4	Calculation
6.4.4	Estimation of particle size for powders and other small dosage forms
6.4.4.1	General
6.4.4.2	Apparatus
6.4.4.3	Procedure
6.4.4.4	Calculation
6.4.5	Estimation of the pH-value of liquids, solutions or suspensions by potentiometric determination
6.4.5.1	General
6.4.5.2	Procedure
6.4.6	Dissolution test for solid dosage forms
6.4.6.1	General
6.4.6.2	Reagents
6.4.6.3	Apparatus
6.4.6.4	Procedure for the production of test sample solutions
6.4.6.5	Estimation of the content of active substances in the test sample solutions
6.4.6.6	Calculation
6.5	Estimation of the content of residual solvents
6.5.1	General
6.5.2	Types of typically used solvents
6.5.2.1	Solvents to be avoided (class 1)
6.5.2.2	Solvents to be limited (class 2)
6.5.2.3	Solvents with low toxic potential (class 3)
6.5.3	Reagents
6.5.4	Sample preparation
6.5.5	Apparatus
6.5.6	Procedure
6.5.7	System suitability
6.5.8	Calculation
6.6	Stability of TCM products
6.6.1	General
6.6.2	Estimation of the stability of TCM products